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Dkt. 2048/57906-A/JPW/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: William C. Olson and Paul J. Maddon

December 16, 1999

Examiner: Emily Le Group Art Unit: 1648

For:

Filed:

SYNERGISTIC INHIBITION OF HIV-1 FUSION AND

ATTACHMENT, COMPOSITIONS AND ANTIBODIES THERETO

1185 Avenue of the Americas New York, NY 10036

January 7, 2005

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Serial No.: 09/464,902

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c) and §1.97(e)(1) to supplement the Information Disclosure Statements filed on June 19, 2000, June 14, 2001, September 2, 2003 and October 4, 2004 in connection with the above-identified application.

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**) and attached hereto as Exhibits 1-7, respectively:

- PCT International Application Publication No. WO 97/45543 A, published December 4, 1997 (Exhibit 1);
- PCT International Application Publication No. WO 97/47318 2. A, published December 18, 1997 (Exhibit 2);
- 3. Ghorpade, A., Xia, M.Q., Hyman, B.T., Persidsky, Y., Nukuna, A., Bock, P., Che, M., Limoges, J., Gendelman, H.E.

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Page 2

and Mackay, C.R. (1998) Role of the beta-chemokine receptors CCR3 and CCR5 in human immunodeficiency virus type 1 infection of monocytes and microglia. J. Virol. 72: 3351-3361 (Exhibit 3);

- 4. Schols, D., Proost, P., Struyf, S., Wuyts, A., De Meester, I., Scharpe, S., Van Damme, J. and De Clercq, E. (1999) CD26-processed RANTES(3-68), but not intact RANTES, has potent anti-HIV-1 activity. Antiviral Res. 39: 175-187 (Exhibit 4);
- 5. Simmons, G., Clapham, P.R., Picard, L., Offord, R.E., Rosenkilde, M.M., Schwartz, T.W., Buser, R., Wells, T.N., Proudfoot, A.E. (1997) Potent, inhibition of HIV-1 infectivity in macrophages and lymphocytes by a novel CCR5 antagonist. Science 276: 276-279 (Exhibit 5);
- 6. Lehner, T., Doyle, C., Wang, Y., Babaahmady, K., Whittall, T., Tao, L., Bergmeier, L. and Kelly, C. (2001) Immunogenicity of the extracellular domains of C-C chemokine receptor 5 and the in vitro effects on simian immunodeficiency or HIV infectivity. J. Immunol. 166: 7446-7455 (Exhibit 6); and
- 7. Wu, L., Paxton, W.A., Kassam, N., Ruffing, N., Rottman, J.B., Sullivan, N., Choe, H., Sodroski, J., Newman, W., Koup, R.A. and Mackay, C.R. (1997) CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1 in vitro, J. Exp. Med. 185: 1681-1691 (Exhibit 7).

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO 1449.

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According to 37 C.F.R. §1.97(c)(1), an Information Disclosure Statement shall be considered by the U.S. Patent and Trademark Office if filed after the period specified in §1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a final action under §1.113, a notice of allowance under §1.113, or an action that otherwise closes prosecution in the application, and is accompanied by one of (1) the statement specified in 37 C.F.R. §1.97(e)(1) or §1.97(e)(2), or (2) the fee set forth in 37 C.F.R. §1.17(p).

Pursuant to 37 C.F.R. §1.97(e)(1), applicants hereby state that each of the above-cited references 1-5 was first cited in a Supplementary Partial European Search Report issued October 8, 2004 in connection with European Patent Application No. 99966466.7-2402, a foreign counterpart of the subject application, not more than three months prior to the filing of this Supplemental Information Disclosure Statement. A copy of this European Search Report is attached hereto as **Exhibit B**.

Applicants note that PCT International Application Publication No. WO 98/18826, Wu et al. (1997) J. Exp. Med. 186: 1373-1381, and the Ylisastigui et al. (1998), Mcknight et al. (1997), and Olson et al. (1999) references cited in the above-identified European Search Report (Exhibit B) are not listed herein because these references were previously made of record in the subject application, having been cited to the Examiner in the Supplemental Information Disclosure Statement filed October 4, 2004.

Applicants note also that the above-listed references 6 and 7 were previously cited to the Patent Office as references 15 and 16, respectively (Exhibits P and Q, respectively), in a Supplemental Information Disclosure Statement filed September 2,

Applicants:

William C. Olson and Paul J. Maddon

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2003 in connection with the subject application. Copies of these references are being re-submitted to the Patent Offices since they were inadvertently omitted from the Supplemental Information Disclosure Statement filed October 4, 2004. This October 4, 2004 Supplemental Information Disclosure Statement contained copies of references which applicants had previously submitted to the Patent Office but which could not be located by the Examiner. Applicants note that the above-listed reference 7 is also cited in the October 8, 2004 European Search Report (Exhibit B).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. \$1.97(c)(1) and \$1.97(e)(1), no fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria,

Patents, P.O. VA 22313-1450

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EXAMINER

SIGNATURE

U.S. Department of Commerce Patent and Trademark Office

RMATION DISCLOSURE STATEMENT (Use several sheets if necessary)

Application Number	09/464,902 December 16, 1999 William C. Olson et al.			
Filing Date				
First Named Inventor				
Art Unit	1648			
Examiner Name	Emily Le			
Attorney Docket No.	2048/57906-A/JPW/AJD			

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Examiner Initials*	Cite No. ¹	Foreign Patent Document Cou Code ³⁻ Number ⁴⁻ Kind Code ^{5 (if k}	ntry nown)	Publication Date MM-DD-YYYY		Document Document	T ⁶		
	1 WO/9745543 A					Combadiere, Chrisophe et al.			
	2	WO/9747318 A		12-18-19	997	Allaway, Graham P. et al.			
		NON PATE	NT I	LITERATU	RE I	DOCUMENTS			
Examiner Initials	Cite No.1								
	3	GHORPADE, A., XIA, M.Q., HYMAN, B.T., PERSODSKY, Y., NUKUNA, A., BOCK, P., CHE, M., LIMOGES, J., GENDELMAN, H.E. and MACKAY, C.R. (1998) Role of the beta-chemokine receptors CCR3 and CCR5 in human immunodeficiency virus type 1 infection of monocytes and microglia. J. Virol. 72: 3351-3361; SCHOLS, D., PROOST, P., STRUYF, S., WUYTS, A., DE MEESTER, I., SCHARPE, S., VAN DAMME, J. and DE CLERCQ, E. (1999) CD26-processed RANTES(3-68), but not intact RANTES, has potent anti-HIV-1 activity. Antiviral Res. 39: 175-187;							
	4								
	5	SIMMONS, G., CLAPHAM, P.R., PICARD, L., OFFORD, R.E., ROSENKILDE, M.M., SCHWARTZ, T.W., BUSIER R., WELLS, T.N., PROUDFOOT, A.E. (1997) Potent inhibition of HIV-1 infectivity in macrophages and lymphocytes by a novel CCR5 antagonist. Science 276: 276-279;							
	6	LEHNER, T., DOYLE, C., WANG, Y., BABAAHMADY, K., WHITTALL, T., TAO, L., BERGMEIER, L. and KELLY, C. (2001) Immunogenicity of the extracellular domains of C-C chemokine receptor 5 and the in vitro effects on simian immunodeficiency or HIV infectivity. J. Immunol. 166: 7446-7455; and							
	7	WU, L., PAXTON, W.A., KASSAM, N., RUFFING, N., ROTTMAN, J.B., SULLIVAN, N., CHOE, H., SODROSKI, J., NEWMAN, W., KOUP, R.A. and MACKAY, C.R. (1997) CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1 in vitro, J. Exp. Med. 185: 1681-1691.							

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds of Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English Language Translation is attached.

DATE CONSIDERED

Applicants: William C. Olson, et al.

Serial No.: 09/464,902 Filed: December 16, 1999

Exhibit A